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Development of a core minimum data set to advance real-world evidence generation for uterine fibroids treatment technologies

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ABSTRACT

Objectives The accumulation of data through a prospective, multicenter coordinated registry network (CRN) is a robust and cost-effective way to gather real-world evidence on the performance of uterine fibroids treatment technologies for device-based and intervention-based studies. To develop the CRN, a group of uterine fibroids experts, consisting of representatives from professional societies, the US Food and Drug Administration, academia, industry, and the patient community, was convened to discuss the role and feasibility of the CRN and to identify the core data elements needed to assess uterine fibroid treatment technologies.

Design A Delphi method approach was employed to achieve consensus on a core minimum data set for the CRN. A series of surveys were sent to the panel and answered by each expert anonymously and individually. Results from the surveys were collected, collated, and analyzed by a study design team from Weill Cornell Medicine. Questions for the next round were based on the analysis process and discussed with group members via a conference call. This process was repeated twice over a 3-month time period until consensus was achieved.

Results Twenty-nine experts participated in the Delphi surveys, which began with an initial list of 200 data elements. The working group reached final consensus on 97 data elements capturing patient medical history, imaging data, procedure-related data, post-procedure data, and long-term follow-up data.

Conclusions The CRN successfully convened an expert panel on uterine fibroids treatment technologies and used the Delphi method to produce a consensus-based core set of data elements. These identified data elements include important outcomes related to efficacy and safety and thus, influence patient, provider, and regulatory decision-making about treatments for uterine fibroids. Finally, the core data elements provide the foundation of the infrastructure needed for the CRN that will allow for the comparative study of uterine fibroid treatment devices and technologies.

KEY MESSAGES

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT?

⇒ Despite the high prevalence of uterine fibroids, evidence on the relative safety and effectiveness of available uterine fibroid interventions remains sparse. In part, this is due to a lack of interoperable and harmonized real-world data needed to conduct such comparative effectiveness analyses.

WHAT ARE THE NEW FINDINGS?

⇒ Regulators, clinicians, patients, and manufacturers were engaged to conduct a Delphi process to reach consensus on the core data elements needed to create the CRN. Stakeholders identified 97 core data elements applicable to both existing and new uterine fibroid treatment technologies that would enter the market in the future.

HOW MIGHT THESE RESULTS AFFECT FUTURE RESEARCH OR SURGICAL PRACTICE?

⇒ The core data elements will provide the foundation of the infrastructure needed for the CRN to collect real-world data on the comparative safety and effectiveness of uterine fibroid treatment devices and technologies. This will enable generation of novel real-world evidence that will influence patient, provider, and regulatory decision-making about treatments for uterine fibroids.

INTRODUCTION

Uterine fibroids (also known as leiomyoma) are growths that develop in the uterus. These benign growths can vary in size, number, and symptomatology. According to the Department of Health and Human Services,[1] between 20% and 80% of women develop fibroids by age 50. In addition to existing pharmaceutical treatments, there are several interventions that are used to treat fibroids or

their symptoms, including hysterectomy, myomectomy, radiofrequency ablation, uterine artery embolization, endometrial ablation, and magnetic resonance-guided focused ultrasound. Treatment decisions consider many factors, including experienced symptoms, size and location of the fibroids, patient's age, patient preferences regarding uterine sparing procedures, and the provider's clinical expertise and experience.[2] Treatment decisions also consider the risk of an occult uterine sarcoma in a woman undergoing surgical intervention for presumed fibroids.[3]

Despite the large burden of disease, evidence on the relative safety and effectiveness of available uterine fibroid interventions remains sparse.[4] Given the paucity of comparative studies, there is a clear need for the systematic collection of post-market real-world data for women undergoing treatments using medical devices, with careful consideration of which patient characteristics, procedural data, and health outcomes are most important to capture from a clinical perspective. Premarket studies for uterine fibroid treatment technologies include a relatively small number of patients compared with the large number of women affected by fibroids. Systematic post-marketing collection of data provides an opportunity to understand device performance in the broader use population and to identify potentially rare but serious complications, such as undiagnosed leiomyosarcoma. Additionally, because many women affected by fibroids have an interest in maintaining their fertility,[5 6] systematic methods for capturing reproductive outcomes data in future pregnancies may be possible with large numbers of subjects providing post-market data.

To enable this type of post-market surveillance, we identified the need to create a Coordinated Registry Network (CRN)[7 8] that would be capable of generating real-world data to evaluate the safety and effectiveness of technologies used for uterine fibroids. Foreseeing the potential evolution of technologies used to treat uterine fibroids, stakeholders acknowledged the importance of creating a core minimum data set that would be applicable to multiple technologies for uterine fibroids, including new devices that enter the market in the future. As a first task within this CRN, we used the Delphi method to reach consensus on a core minimum data set for the study of current and future devices and surgical interventions for uterine fibroids.

METHODS

On September 15, 2017, stakeholders from the US Food and Drug Administration (FDA), industry, non-profit organizations, patient advocacy groups, payers, professional society leaders, academia, and clinical experts met at the FDA White Oak Campus in Silver Spring, Maryland, to launch the CRN by discussing the current landscape of registries evaluating uterine fibroid treatment technologies and the perspectives of each major stakeholder.[9] In the afternoon, a breakout session was held for stakeholders to propose data elements that should be included in the Delphi process to build the core minimum data set. Following the meeting, the uterine fibroids working group created an initial set of data elements based on the September 15, 2017, meeting, a review of the literature, regulatory expectations, and existing research efforts. The uterine fibroid working group consisted of 29 members, including practicing physicians, researchers, reviewers and medical officers from the FDA, industry representatives, and one patient partner who represented a large group of patients from the Fibroid Foundation.[10] The full list of working group members is reported in online supplemental file 1. In the fall of 2017, the group streamlined their initial list from more than 350 data elements to about 200 data elements that could be used to begin the Delphi process.

The Delphi method is a group decision-making technique that was developed by Olaf Helmer and Norman Dalkey as part of an Air Force-sponsored Rand Corporation study in the early 1950s, for the purpose of addressing a specific military problem.[11] The standard group decision-making technique, the consensus panel approach, brings experts together in a room to discuss an issue until a consensus emerges. The challenges with this traditional approach are that one person with a strong personality can have a large effect on the decision, and a lack of anonymity may introduce response bias. The Delphi method was developed to retain the strength of a joint consensus, while removing the potential bias from group dynamics and face-to-face responses. With the Delphi method, group input is received through a series of anonymous surveys, which are sent to a pre-selected group of experts. The questionnaires are answered anonymously and individually by each member of the group. Each survey also provides an opportunity for group members to introduce new options and suggestions in between rounds. Survey results of each round are collected, collated, and analyzed by a design team. Typically, responses with strong consensus (eg, >50%) are maintained for the next round, and responses that lack consensus are automatically dropped (eg, <50%). Subsequently, the results are summarized and discussed with the group. The questions for the next round are based on this analysis and discussion process. This process is repeated until a group consensus is reached. Usually, only two iterations are needed but sometimes as many as six rounds are needed before a consensus is reached.[11–14] Most of these methodologies are standardized for CRN purposes and also used in maturity model framework development,[15] and core minimum data set development for sterilization,[16] pelvic organ prolapse,[17] peripheral artery interventions,[18] and prostrate ablation.[19]

The Delphi process for the uterine fibroids working group was initiated and completed over a 3-month period from June 2018 to August 2018. Two rounds of surveys were designed and administered by the analysis team at Weill Cornell Medicine and sent to the expert panelists through a secure anonymous online questionnaire

(https://www.surveymonkey.com). The data collection forms from the COMPARE-UF registry[20] were used as an initial basis for candidate data elements. The panelists were instructed to vote on which variables, from a clinical perspective, are the most important variables to study the safety and effectiveness of medical devices and procedures used to treat uterine fibroids. The first-round Delphi survey results were analyzed by the analysis team and discussed in a series of conference calls with the working group co-chairs. Any variable with less than 50% consensus was removed from the list of data elements and any variable with greater than 50% consensus was retained for the second-round survey. These results and open response suggestions were presented and discussed with the full working group until consensus was achieved on how to proceed for each variable and open response comment. For example, if a working group member saw value in one of the variables that received less than 50% consensus, the working group member would have the opportunity to bring this up for discussion in the working group conference calls and argue the case to retain this variable. The analysis team incorporated the results of these discussions into the design of the second-round survey and subsequently distributed the survey to the working group. The same process was repeated until the consensus was achieved on the final core minimum data set in August 2018. Although the Delphi process was completed in August 2018, the final core minimum data set was not fully approved until after a formal review process by the FDA was completed in 2019. On completion of this process, the coauthors drafted the manuscript from 2019 to 2020, and this manuscript also went through a formal review and approval process which was completed by the FDA in early 2021.

RESULTS

Overview

The uterine fibroids working group consisted of 29 expert members, including practicing physicians, reviewers and medical officers from the FDA, researchers, industry representatives, and one patient representative. The working group co-chairs reduced the initial list of more than 350 potential data elements to 200 data elements that were included in the Delphi process. Completion of the Delphi surveys and group consensus resulted in the selection of 97 data elements and are reported in the appendix. These data elements were identified as relevant to surgical devices used for the treatment of uterine fibroids. Patient demographic variables (age, race, etc.) were not included in the Delphi selection process as a standard, harmonized set of demographic variables was selected based on work already conducted by a multistakeholder project sponsored by the Pew Charitable Trusts.[21] The final data elements may be entered by patients, by physicians, or through a hybrid approach based on available technology.

Medical, reproductive, and gynecologic history

For patient medical history, there was consensus on capturing the presence of relatively common medical conditions among reproductive aged women that might affect complication risk during or after a procedure. These conditions included hypertension, diabetes, thyroid disease, and a history of thrombosis. Gynecologic conditions that frequently coexist or produce similar symptoms to uterine fibroids and which could affect treatment decisions and/or the likelihood of symptom relief, such as endometriosis and adenomyosis, were also identified. Because abnormal uterine bleeding is the most frequent symptom associated with uterine fibroids, there was consensus on including data on menstrual regularity, heaviness of flow, and whether the abnormal bleeding had resulted in anemia, with or without a transfusion (as a marker of severity). Although there was consensus on the value of these data, the participants recognized that there is considerable variability in how this information is elicited from patients and recorded by clinicians, and that further work on reaching consensus on standards for reporting is needed. There was consensus on including data on previous pregnancy, including number of pregnancies, outcomes (miscarriage, abortion, live birth, stillbirth), gestational age, and delivery type. Pregnancy-related data elements were considered important for several reasons, including a potential association between fibroids and outcomes, the impact of mode of delivery on choice of treatment approach (such as scarring from previous cesarean sections), concordance with other WHT-CRN registries, and, importantly, the potential for using those same elements as outcomes for uterine-preserving treatments.

Data elements specific to fibroid history included current symptoms (bleeding, cyclic pain, non-cyclic pain, bulk symptoms, recurrent miscarriage), history and year of any prior procedures (abdominal, hysteroscopic, laparoscopic/robotic, or vaginal myomectomy, focused ultrasound, endometrial ablation, radiofrequency ablation, or uterine artery embolization), and current medical treatments (hormonal birth control, tranexamic acid, gonadotropin-releasing hormone (GnRH) agonists, or non-steroidal anti-inflammatory drugs).

Imaging data

There was consensus on including specific data elements from any imaging studies obtained prior to the procedure, including date, type of modality, and fibroid characteristics—location, size, number visualized, and number measured, as well as uterine dimensions if recorded. As with menstrual history, there was a recognition that there is considerable variability in how fibroid imaging is reported and recorded and that further work on developing standards was needed. There was also consensus that any radiologic suspicion of adenomyosis, endometriosis, or a potentially malignant uterine lesion should also be recorded.

Procedure data

The participants reached consensus on minimal data elements for all procedures, including whether the originally planned procedure was performed, procedure and discharge date, an identifier for the primary surgeon, occurrence of any intraoperative adverse events and an assessment about the relationship between the event and any devices used, other relevant intraoperative findings (eg, presence of adhesions), and other procedures performed (eg, oophorectomy). Relevant pathology findings, depending on the procedure, include uterine and ovarian pathology, uterine weight (for hysterectomy), number and cumulative weight of excised fibroids (for myomectomy), and use of morcellation (including device and containment status). For procedures that do not specifically remove tissues, such as uterine artery embolization, MRI-guided focused ultrasound, and radiofrequency ablation, stakeholders agreed to include details on the embolized arteries or the number of fibroids that were treated.

Post-procedure (short-term and long-term) data

At every follow-up interval, there was consensus on collecting data on post-procedure adverse events, whether cancer was diagnosed during follow-up, and treatment failure or recurrence of symptoms. Treatment failure and recurrence of symptoms was defined as the need for another fibroid procedure. If a cancer diagnosis was indicated, working group members agreed that it should be further specified if the cancer was leiomyosarcoma. There was also agreement that other measures of symptom recurrence, such as changes in a validated patient-reported outcome measure (PROM) or the need for new medical therapy, would be helpful. However, because of the lack of current standards for the use of PROMs in clinical practice, it was agreed that the chosen outcome measures were more reproducible and would capture the most important safety outcomes. As noted above, there was also recognition that pregnancy outcomes are important for many patients undergoing treatment for uterine fibroids, but that the data elements collected as part of the medical and gynecologic history would capture the most relevant outcomes at visits after the index procedure.

Informatics work

To create a CRN that is capable of conducting patient-centered outcomes research for multiple women's health conditions (WHT-CRN), the FDA partnered with the Office of the National Coordinator for Health Information Technology (ONC), the National Library of Medicine (NLM), and a multistakeholder community coordinated by MDEpiNet in a large project funded by the Patient-Centered Outcomes Research Trust Fund (PCORTF) administered by the Office of the Assistant Secretary for Planning and Evaluation of the US Department of Health and Human Services.[22] Through this project, core minimum data sets were concurrently being developed for stress urinary incontinence, pelvic organ prolapse, sterilization, and long-acting and reversible contraception. In order to create a CRN capable of evaluating medical devices used for all of these conditions, it was imperative to harmonize common data elements among all of the clinical areas to ensure interoperability of data sets stemming from future registries. After the core minimum data sets were developed for each of these clinical conditions, the project team formed an informatics team consisting of representatives from the National Institutes of Health (NIH), FDA, NLM, and ONC to lead the harmonization of each of the core data sets.

This group identified, compared, and aggregated data elements for each of the clinical areas prior to modeling. Any data elements that were common in at least two of the clinical areas were reviewed and refined through an iterative and collaborative process with both the informatics team and the clinical working groups, resulting in an initial set of harmonized common data elements. Modeling of data elements entails creating a form for each of the clinical registries in the NIH Common Data Elements (CDE) repository. Each form contained the full harmonized set of data elements with their associated permissible values linked to standardized codes and the data elements required in the Health Level Seven International (HL7) profiles. Code sets were included from standard clinical vocabularies, including the Value Set Authority Center,[23] the Current Procedural Terminology, the Healthcare Common Procedure Coding System, and the International Classification of Diseases. The clinical working group reviewed these forms and provided feedback before the data elements were added to the HL7 Women's Health Technologies (WHT) CRN Implementation Guide (IG).[24]

ONC will use the harmonized list of data elements in the WHT-CRN IG to define the data collection instruments and collect data for testing during pilot activities. The WHT-CRN IG is built to be an interoperable data exchange standard that consists of the resources, profiles, value sets, capability statements and specific implementation guidance for organizations (eg, hospitals, provider groups, researchers) to receive system data that meet current WHT-CRN use cases. Please see figure 1A,B for illustrations of how the WHT-CRN data will be collected and accessed by organizations. The WHT-CRN IG will also provide a platform for new use cases. The goal of this project is to make women's health data available for exchange among providers and authorized researchers. Because this is also a goal of the Patient-Centered Outcome Research Network (PCORNet) and this project has been funded by the PCORTF, the WHT-CRN IG requirements have been drawn from the PCORNet use cases and implementations.[25] Additional implementations that support this IG include the US-Core IG (mapped to the ONC 2015 Edition Common Clinical Data Set; Structured Data Capture Fast Health Interoperability Resources (FHIR) IG (the framework for questionnaire and questionnaire response resources); and the Patient-Reported Outcomes

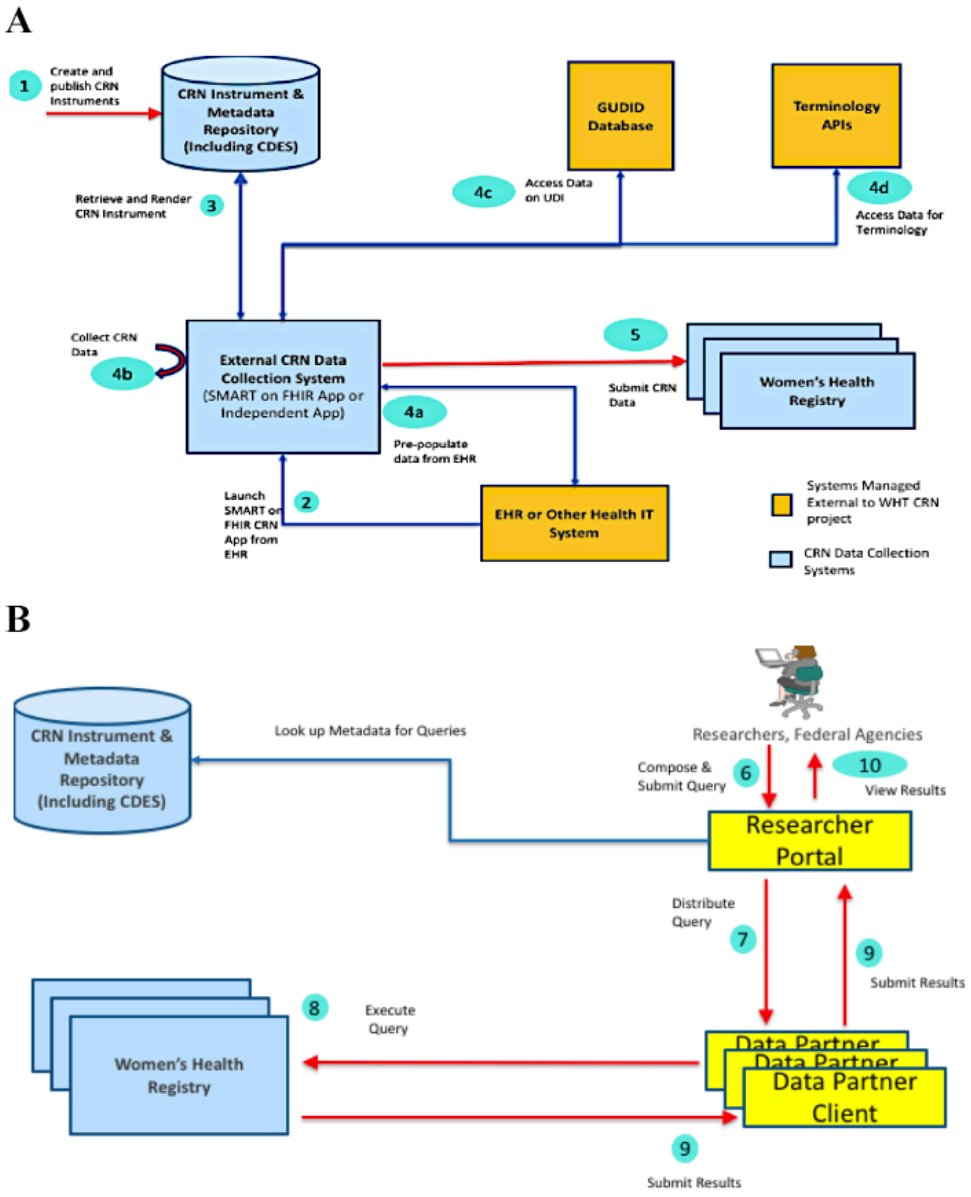

Figure 1 The abstract model, actors, and the data flow for WHT-CRN data collection. (A,B) Detail the capabilities required to implement a WHT-CRN workflow from the point of data collection to access of that data for research. The abstract model for collecting WHT-CRN data focuses on collection from patients undergoing various treatments of interest using a combination of clinical care delivery systems like EHRs and independent applications. The abstract model for accessing collected data from women's health registries focuses on the ability of researchers to access the data currently collected and persisted in the registries. CRN, coordinated registry network; EHRs, electronic health records; IT, information technology; WHT, Women's Health Technologies.

(PRO) FHIR IG (the framework for the Questionnaire Resource for capturing Patient Reported Outcome data). ONC will create new profiles and extensions for data elements that are not mapped to existing profiles. Registries will pilot the WHT-CRN FHIR IG in a test production environment (eg, clinical or provider setting), and/or manufacturing setting for CRN specific capabilities.[26] Please see online supplemental file 2 for further clarification on these concepts and a full list of acronyms used in this manuscript.

During the project, registry participants and CRN partners will continuously update the core common data elements within the IG and the sets of individual registry core data elements that are not represented in the IG. NLM will continue modifying the Pilot Harmonization form in the NIH CDE repository to supply the most recent vocabulary in the IG. NLM plans to update the CDE repository to support hosting, editing, harmonization, and export of the WHT-CRN data elements and other future CRN data elements. The data will be in machine readable format for use by data collection software applications for easier harmonization and reuse by stakeholders, specifically registries capturing device-related information on conditions affecting women. Technical assistance from NLM to support these efforts will include video tutorials and guides. In addition, throughout the pilot, the

FDA and other stakeholders will continue monitoring and evaluating the implementation of the IG and the harmonized data set within clinical registries to support the refinement process. Patient data will be protected by institutional firewalls at each of the CRN's clinical sites, and authorized researchers will only be able to access CRN data after going through a data sharing agreement process that will be managed by the MDEpiNet Coordinating Center.

DISCUSSION

Single-purpose registries face many challenges in addressing questions involving multiple therapies and conditions. By leveraging fewer resources to collect predefined data for a greater number of conditions and therapies, this CRN will improve real-world evidence generation while saving time and reducing cost. We envision that this CRN will demonstrate that data from the different sources (eg, electronic health records, registries) can be used to: (1) evaluate the effectiveness (ie, quality of life) and safety associated with differing treatment options for uterine fibroids; (2) provide a framework for clinical studies to be conducted within the infrastructure, including industry-sponsored studies conducted for pre-market and/or post-market regulatory purposes; and (3) allow healthcare providers to track surgeon volume, patient outcomes, and quality measures for quality improvement activities and to fulfill upcoming requirements for the Centers for Medicare & Medicaid Services Merit-based Incentive Payment System and maintenance of certification requirements.

By using a Delphi process that engaged multiple stakeholders with varying perspectives on uterine fibroid treatment devices, we were able to achieve consensus on a minimum data set of variables capable of evaluating the performance of uterine fibroid treatment devices and technologies. One of the key steps in creating the CRN for uterine fibroids was identifying a core data set that would require minimal data entry by clinicians but would also be comprehensive enough to conduct safety and effectiveness studies. It was also important that the core data set would be well-suited for new technologies that enter the market in the future. The included stakeholders foresee many applications for new uterine fibroid treatment devices and technologies in the coming years and believe that the data elements captured in this registry are generalizable to both existing devices and novel technologies that may enter the market in the future.

Because the correlation between fibroid anatomy and symptoms is poor, 'objective' measures of success such as residual fibroid volume are not particularly helpful for evaluating effectiveness and do not allow for comparisons between procedures which affect fibroid size and those which physically remove the fibroids or the uterus itself. In addition, the lack of standards for reporting fibroid imaging further limits the utility of anatomic measurements as a relevant outcome. The participants focused on patient-reported outcomes related to symptoms but recognized that there is also a lack of clinical consensus on how best to measure and report fibroid-related symptoms. If validated patient-reported instruments such as the Uterine Fibroid Symptom Health-Related Quality of Life (UFS-QoL)[27] can be easily incorporated into clinical practice (perhaps through patient-facing electronic portals or applications), adding them to this core dataset would be important.

There are both general and specific limitations to our methodology. Although multiple stakeholders were represented, the final consensus obviously includes trade-offs and may not represent the priorities of individual stakeholders or those who did not participate. In addition, the desire to capture data that are currently routinely captured as part of clinical care means that other important outcomes are not included. In particular, because validated quality-of-life instruments are not regularly collected as part of routine practice, treatment effectiveness within the current data elements can only be estimated through identification of additional procedures after the index treatment. Nonetheless, our results are strengthened by the fact that all participants shared an equal influence on the outcomes and potential bias from group dynamics and face-to-face responses was avoided through the Delphi method.

In conclusion, the data elements identified through the consensus process meet several criteria. They represent items that are currently routinely captured as part of the clinical record, they include factors that influence patient and provider decisions about treatment options which may influence outcomes (eg, past treatments, pregnancy history, uterine anatomy), and include important outcomes related to safety. In addition, the final common data elements were developed with input from multiple stakeholders, including patients, clinicians, researchers, manufacturers, and the FDA. Ultimately, the establishment of a national infrastructure for collecting these data elements will enable the accrual of high-quality data on devices and technologies used for uterine fibroids in the context of a multipurpose CRN. Additionally, the WHT-CRN will address FDA strategic priorities by increasing the use of real-world evidence, engaging patient partners, and promoting collaborative communities.[28]

APPENDIX

Uterine Fibroids Data Elements*		
Medical history		
General medical history	High blood pressure Diabetes Thyroid problems	Blood clots in legs or lungs Endometriosis Adenomyosis

Uterine Fibroids Data Elements*		
Menstrual cycle/flow	Are your periods regular (in timing and predictable within 5 days)?	Do you have a history of anemia related to your heavy periods or fibroids? If yes, did this anemia ever require A blood transfusion? Heaviness of flow
Pregnancy history	Have you ever been pregnant? If yes, how many pregnancies have You had? For each pregnancy, outcome:	For each pregnancy, when did you Deliver? For each pregnancy, what type of Delivery did you have?
Uterine fibroid history	Are you currently having any symptoms related to your fibroids?	If yes, select all fibroid-related Symptoms you are currently Experiencing
Prior uterine fibroid procedures	How many prior procedures? Abdominal myomectomy (open surgery to remove the fibroids, abdominal incision) If yes, year of procedure Hysteroscopic myomectomy (telescope inside the uterus removing fibroids) If yes, year of procedure Laparoscopic or robotic myomectomy, (davinci robotic surgery) If yes, year of procedure Myomectomy, vaginal (open surgery to remove fibroids, vaginal incision) If yes, year of procedure Focused ultrasound (exablate; sonalleve) If yes, year of procedure	Endometrial ablation (any type; examples include: novasure impedance, her option, hydrotherm, microsulis (microwave), thermachoice balloon, resectoscope) If yes, year of procedure Radiofrequency ablation (acessa) (destroying the fibroid with heat from a needle that is inserted into the fibroid using a telescope inserted through a small abdominal incision) If yes, year of procedure Uterine arterial embolization/ uterine fibroid embolization (uae) (inserting particles to block fibroid blood vessels using a slender, flexible tube) If yes, year of procedure
Current uterine fibroid therapies or supplements	Do you use hormonal birth control? If yes, what do you use it for: If yes, what type of hormonal birth Control?	Tranexamic acid (lysteda) Lupron Anti-inflammatory medication or nsaids (e.g., Ibuprofen, motrin, aleve, advil, anaprox, etc.)
Imaging data		
Imaging data	Date of imaging Type of modality Fibroid location Fibroid sizes/ measurement How many fibroids are visualized (e.g., Present or seen)?	How many fibroids are measured? Report all dimensions listed Adenomyosis? Endometriosis? Uterine lesion suspicious for malignancy?
Procedure data		
Planned procedure	Planned procedure Was the planned procedure completed?	If no, was another uterine fibroid Procedure performed?
All procedures	Procedure date Discharge date Primary surgeon Primary procedure performed Intraoperative adverse events (aes) If any aes, was ae device-related?	Ovarian pathology findings Uterine pathology findings Other operative findings Estimated blood loss (in cc/ml) Post-operative events Other procedures performed
Hysterectomy	Surgical route Route for removal of uterus Uterine weight	Was morcellation used? If yes, was morcellation contained? If yes, what device was used to Morcellate and/or contain tissue?
Abdominal myomectomy	Incision type # of excised fibroids	Cumulative weight of excised fibroids
Hysteroscopic myomectomy	Cumulative weight of excised fibroids	# of excised fibroids
Endometrial ablation	Type	
Laparoscopic or robotic myomectomy	Was morcellation used? If yes, was morcellation contained? If yes, what device was used to Morcellate and/or contain tissue?	Cumulative weight of excised fibroids # of excised fibroids
Uterine artery embolization	Uterine arteries embolized?	Ovarian arteries embolized?
Magnetic resonance-guided focused ultrasound	Device # of treated fibroids	Injury to other structures diagnosed post-procedure
Radiofrequency ablation via laparoscopy	# of fibroids visualized on ultrasound	# of treated fibroids
Post-procedure data		
Post-procedure data	Treatment failure: did you have another fibroid procedure? Was cancer found during follow up?	If cancer was found, was it lms? Post-procedure adverse events
Long-term follow-up data		
Long-term follow-up data	Treatment failure: did you have another fibroid procedure? Was cancer found during follow up?	If cancer found, was it lms? Post-procedure adverse events

*These data elements may be entered by patients, by physicians, or through a hybrid approach based on available technology.
Note: This table originally appeared in The Women's Health Technologies Coordinated Registry Network (WHT-CRN) report.[13]

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Contributors AS and DM-D initiated the collaborative project. All authors participated in the initial stakeholder meeting to conceptualize the project and design the study protocol. CEB designed the Delphi surveys, collated, and analyzed the Delphi survey results, managed the Delphi process, and drafted the first version of the manuscript. EM and VJ served as working group co-chairs, provided clinical/epidemiological insights on the Delphi survey results, and co-lead discussions with working group members. All authors served as members of the working group, participated in discussions throughout the Delphi process, reviewed manuscript drafts, and participated in editing and revising the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. CEB is the guarantor.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval The Women's Health CRN work was approved under IRB #1511016772. Prior to initiation of this study, an MDEpiNet oversight committee was established, and a written protocol was developed which prespecified the

study methods. The Delphi process involved feedback from Women's Health CRN partners and as such no other regulatory requirements were considered relevant.

Provenance and peer review Commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data that support the findings of this study are available from the corresponding author, CEB, upon reasonable request.

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